

WHAT IS CLAIMED IS:

1                   1.       A vascular prosthesis comprising:  
2                   an expandible structure which is implantable within a body lumen; and  
3                   means on or within the structure for releasing methylprednisolone into the  
4                   body lumen to inhibit smooth muscle cell proliferation.

1                   2.       A prosthesis as in claim 1, wherein methylprednisolone is released at a  
2                   rate between 5 µg/day to 200 µg/day.

1                   3.       A prosthesis as in claim 1, wherein methylprednisolone is released at a  
2                   rate between 10 µg/day to 60 µg/day.

1                   4.       A prosthesis as in claim 1, wherein methylprednisolone is released at  
2                   an initial phase wherein a rate of methylprednisolone release is between 0 µg/day to 50  
3                   µg/day and a subsequent phase wherein a rate of methylprednisolone release is between 5  
4                   µg/day to 200 µg/day.

1                   5.       A prosthesis as in claim 1, wherein methylprednisolone is released at  
2                   an initial phase wherein a rate of methylprednisolone release is between 5 µg/day to 30  
3                   µg/day and a subsequent phase wherein a rate of methylprednisolone release is between 10  
4                   µg/day to 100 µg/day.

1                   6.       A prosthesis as in claim 1, wherein methylprednisolone is released at  
2                   an initial phase wherein a rate of methylprednisolone release is between 40 µg/day to 300  
3                   µg/day and a subsequent phase wherein a rate of methylprednisolone release is between 1  
4                   µg/day to 100 µg/day.

1                   7.       A prosthesis as in claim 1, wherein methylprednisolone is released at  
2                   an initial phase wherein a rate of methylprednisolone release is between 40 µg/day to 200  
3                   µg/day and a subsequent phase wherein a rate of methylprednisolone release is between 10  
4                   µg/day to 40 µg/day.

1                   8.       A prosthesis as in claim 1, wherein methylprednisolone is released at a  
2                   constant rate between 5 µg/day to 200 µg/day.

1                   9.       A prosthesis as in claim 1, wherein a total amount of  
2                   methylprednisolone release is in a range from 100 µg to 10 mg.

1                    10.     A prosthesis as in claim 1, wherein a total amount of  
2 methylprednisolone release is in a range from 300 µg to 2 mg.

1                    11.     A prosthesis as in claim 1, wherein a total amount of  
2 methylprednisolone release is in a range from 500 µg to 1.5 mg.

1                    12.     A prosthesis as in claim 1, wherein a mammalian tissue concentration  
2 of methylprednisolone at an initial phase is within a range from 0 µg/mg of tissue to 100  
3 µg/mg of tissue.

1                    13.     A prosthesis as in claim 1, wherein a mammalian tissue concentration  
2 of methylprednisolone at an initial phase is within a range from 0 µg/mg of tissue to 10  
3 µg/mg of tissue.

1                    14.     A prosthesis as in claim 1, wherein a mammalian tissue concentration  
2 of methylprednisolone at a subsequent phase is within a range from 1 picogram/mg of tissue  
3 to 100 µg/mg of tissue.

1                    15.     A prosthesis as in claim 1, wherein a mammalian tissue concentration  
2 of methylprednisolone at a subsequent phase is within a range from 1 nanogram/mg of tissue  
3 to 10 µg/mg of tissue.

1                    16.     A prosthesis as in claim 1, wherein the expansible structure is a stent or  
2 graft.

1                    17.     A prosthesis as in claim 1, wherein the means for releasing  
2 methylprednisolone comprises a matrix formed over at least a portion of the structure.

1                    18.     A prosthesis as in claim 17, wherein the matrix is composed of a  
2 material which undergoes degradation.

1                    19.     A prosthesis as in claim 17, wherein the matrix is composed of a  
2 nondegradable material.

1                    20.     A prosthesis as in claim 19, wherein methylprednisolone is released by  
2 diffusion through the nondegradable matrix.

1           21.     A prosthesis as in claim 17, wherein the matrix comprises multiple  
2 layers, wherein at least one layer contains methylprednisolone and another layer contains  
3 methylprednisolone, at least one substance other than methylprednisolone, or no substance.

1           22.     A prosthesis as in claim 21, wherein the at least one substance other  
2 than methylprednisolone is an immunosuppressive substance selected from the group  
3 consisting of rapamycin, mycophenolic acid, riboflavin, tiazofurin, mizoribine, FK 506,  
4 zafurin, and methotrexate.

1           23.     A prosthesis as in claim 21, wherein the at least one substance other  
2 than methylprednisolone is an agent selected from the group consisting of anti-platelet agent,  
3 anti-thrombotic agent, and IIb/IIIa agent.

1           24.     A prosthesis as in claim 1, wherein the means for releasing  
2 methylprednisolone comprises a rate limiting barrier formed over at least a portion of the  
3 structure.

1           25.     A prosthesis as in claim 24, wherein methylprednisolone is released by  
2 diffusion through the rate limiting barrier.

1           26.     A prosthesis as in claim 1, wherein the means for releasing  
2 methylprednisolone comprises a reservoir on or within the structure containing  
3 methylprednisolone and a cover over the reservoir.

1           27.     A prosthesis as in claim 1, wherein methylprednisolone is on or within  
2 the expansible structure.

1           28.     A prosthesis as in claim 1, wherein methylprednisolone is disposed  
2 within a matrix or rate limiting membrane.

1           29.     A vascular prosthesis comprising:  
2 an expansible structure implantable within a body lumen; and  
3 a rate limiting barrier on the structure for releasing methylprednisolone into  
4 the body lumen to inhibit smooth muscle cell proliferation;  
5 wherein the barrier comprises multiple layers, each layer comprising parylast  
6 or paralene and having a thickness in a range from 50 nm to 10 microns.

1                   30.     A prosthesis as in claim 29, wherein methylprednisolone is released at  
2 a rate between 5 µg/day to 200 µg/day.

1                   31.     A prosthesis as in claim 29, wherein methylprednisolone is released at  
2 a rate between 10 µg/day to 60 µg/day.

1                   32.     A prosthesis as in claim 29, wherein at least one layer contains  
2 methylprednisolone and another layer contains methylprednisolone, at least one substance  
3 other than methylprednisolone, or no substance.

1                   33.     A vascular prosthesis comprising:  
2 an expansible structure;  
3 a source of methylprednisolone on or within the structure, wherein the  
4 methylprednisolone is released from the source when the expansible structure is implanted in  
5 a blood vessel; and

6 a source of at least one other substance in addition to methylprednisolone on  
7 or within the structure, wherein the at least one additional substance is released from the  
8 source when the expansible structure is implanted in a blood vessel.

1                   34.     A prosthesis as in claim 33, wherein the at least one additional  
2 substance is an immunosuppressive substance selected from the group consisting of  
3 rapamycin, mycophenolic acid, riboflavin, tiazofurin, mizoribine, FK 506, zafurin, and  
4 methotrexate.

1                   35.     A prosthesis as in claim 33, wherein the at least one additional  
2 substance comprises at least one agent selected from the group consisting of anti-platelet  
3 agent, anti-thrombotic agent, and IIb/IIIa agent.

1                   36.     A prosthesis as in claim 33, wherein each source comprises a matrix,  
2 rate limiting membrane, or reservoir.

1                   37.     A method for inhibiting restenosis in a blood vessel following  
2 recanalization of the blood vessel, said method comprising:  
3 implanting a vascular prosthesis in the blood vessel; and  
4 releasing methylprednisolone into the blood vessel so as to inhibit smooth  
5 muscle cell proliferation.

1 38. A method as in claim 37, wherein methylprednisolone is released at a  
2 rate between 5 µg/day to 200 µg/day.

1 39. A method as in claim 37, wherein methylprednisolone is released at a  
2 rate between 10 µg/day to 60 µg/day.

1 40. A method as in claim 37, wherein methylprednisolone is released  
2 within a time period of 1 day to 45 days in a vascular environment.

1 41. A method as in claim 37, wherein methylprednisolone is released  
2 within a time period of 7 days to 21 days in a vascular environment.

1 42. A method as in claim 37, further comprising releasing at least one  
2 other substance in addition to methylprednisolone simultaneously with methylprednisolone  
3 release.

1 43. A method as in claim 37, further comprising releasing at least one  
2 other substance in addition to methylprednisolone sequentially with methylprednisolone  
3 release.

1 44. A method as in claim 42 or 43, wherein the at least one additional  
2 substance is an immunosuppressive substance selected from the group consisting of  
3 rapamycin, mycophenolic acid, riboflavin, tiazofurin, mizoribine, FK 506, zafurin, and  
4 methotrexate.

1 45. A method as in claim 37, wherein the releasing comprises delaying  
2 substantial release of methylprednisolone for at least one hour following implantation of the  
3 prosthesis.

1 46. A method as in claim 45, wherein delaying release comprises slowing  
2 release from a reservoir with a material that at least partially degrades in a vascular  
3 environment over said one hour.

1 47. A method as in claim 45, wherein delaying release comprises slowing  
2 release with a matrix that at least partially degrades in a vascular environment over said one  
3 hour.

1           48.     A method as in claim 45, wherein delaying release comprises slowing  
2 release with a nondegradable matrix that allows diffusion of methylprednisolone through the  
3 nondegradable matrix after said one hour.

1           49.     A method as in claim 45, wherein delaying release comprises slowing  
2 release with a rate limiting barrier that allows diffusion of methylprednisolone through the  
3 barrier after said one hour.

1           50.     A method as in any one of claims 47-49, wherein the prosthesis is  
2 coated with the matrix or barrier by spraying, dipping, deposition, or painting.

1           51.     A method as in claim 37, wherein the prosthesis incorporates  
2 methylprednisolone by coating, spraying, dipping, deposition, chemical bonding, or painting  
3 methylprednisolone on the prosthesis.

1           52.     A method for inhibiting restenosis in a blood vessel following  
2 recanalization of the blood vessel, said method comprising:  
3                 implanting a vascular prosthesis in the blood vessel; and  
4                 releasing methylprednisolone and at least one other substance in addition to  
5 methylprednisolone from the prosthesis when implanted in the blood vessel.

1           53.     A method as in claim 52, wherein the at least one additional substance  
2 is an immunosuppressive substance selected from the group consisting of rapamycin,  
3 mycophenolic acid, riboflavin, tiazofurin, mizoribine, FK 506, zafurin, and methotrexate.

1           54.     A method as in claim 53, wherein the immunosuppressive substance is  
2 mycophenolic acid.

1           55.     A method as in claim 53, wherein the immunosuppressive substance is  
2 mizoribine.

1           56.     A method as in claim 52, wherein methylprednisolone is released  
2 within a time period of 2 days to 3 months.

1           57.     A method as in claim 52, wherein the at least one additional substance  
2 comprises at least one agent selected from the group consisting of anti-platelet agent, anti-  
3 thrombotic agent, and IIb/IIIa agent.

1                    58.     A method as in claim 52, wherein methylprednisolone and the at least  
2     one additional substance are released simultaneously.

1                    59.     A method as in claim 52, wherein methylprednisolone and the at least  
2     one additional substance are released sequentially.